K110037

APR 29 2011

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510(k) Summary of Safety and Effectiveness of PalaXpress ultra

(1) Submitter's name

Heraeus Kulzer, LLC (for Heraeus Kulzer, GmbH)
300 Heraeus Way
South Bend, Indiana 46614

Contact person: Cheryl V. Zimmerman
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Date summary was prepared: 2011-03-11

(2) Name of Device

Trade name – PalaXpress ultra
Classification name – Denture relining, repairing, or rebasing resin (872.376)
Class – II

(3) Substantial equivalence

PalaXpress ultra, liquid and powders, is substantially equivalent with Palapress vario, liquid and powders, 510(k) No. K902115
Main component of both liquids is methyl methacrylate and dimethacrylates, of the powders polymethyl methacrylate

(4) Description of the device

PalaXpress ultra was developed as an auto-polymerizing denture and differs from the substantially equivalent device Palapress vario in the increased fracture resistance compared with that material. The product was developed as an auto-polymerizing universal denture base material.

The product consists of powder in various shades (pink, pink veined, link live, pink opaque, R50 veined, clear, light pink, light reddish pink, shade 200, dark pink) and liquid. 80 ml or 500 ml of liquid is supplied in brown glass bottles in an outer cardboard box, the 100 g or 1000 g powder is supplied in square HD-PE bottles in a outer cardboard box. 12000 g are available upon request.

To make sure denture, powder and liquid are mixed, in a ratio of 30 g : 15 ml (2:1) for the injection procedure, and in a ratio of 10 g powder : 7 ml liquid for the pouring procedure. Polymerization time in the pressure vessel is 30 min, at a water temperature 55°C and a pressure of 2 bar.

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The material has a shelf life of 42 months and complies with the requirements of ISO 20795-1:2008 for denture base polymers.

(5) Intended use

PalaXpress ultra is a denture base material to be used with injection or pouring techniques for fixed and removable dentures:

Injection technique:	Full maxillary and mandibular prostheses
	Implant overdenture
Pour technique:	Implant overdenture
	Partial dentures, multiple or single saddles
	Marginal contour and reshaping
	Repair and additions
	Relines
	Dental splints

(6) Summaries and Conclusion

(a) Technological Characteristics

PalaXpress ultra was developed as an auto-polymerizing resin with increased fracture resistance. In all other properties it is compared with the essentially equivalent auto-polymerizing denture base resin Palapress vario. The attained increase fracture resistance has no influence during the fabrication of the denture, but will, in the final dental prosthesis, benefit the patient in so far as it will not break as easily as a denture fabricated from a conventional auto-polymerizing denture base material.

(b) Nonclinical tests and clinical tests/evaluations

(1) Nonclinical tests: In accordance with the Medical Device Directive 93/42/EEC and National European medical device legislation, any medical device, must be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes an evaluation of biocompatibility in accordance with ISO 10993-1. As PalaXpress ultra is exclusively used for the fabrication, completion, repair or relining of denture bases as well as implant-supported prostheses and dental splints, it can be concluded that there is only contact with the mucosa. The duration of contact of PalaXpress ultra is > 30 days. According to this classification, (DIN EN ISO 10993-1, Table 1) the following tests must be considered:
Cytotoxicity, Sensitization, Irritation / intracutaneous reactivity, Subacute / Subchronic toxicity, Genotoxicity. On the basis of the test results, the biocompatibility of PalaXpress ultra in the aforementioned indication was documented in a biocompatibility evaluation report and the benefit / risk-relation has been judged as positive.

(2) Clinical evaluation

In accordance with the Medical Device Directive 93/24/EEC and National European medical device evaluation, any medical device is requested to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes a clinical evaluation in accordance with MEDDEV 2.7.1, which is intended to critically evaluate the clinical benefits of the medical device in comparison to its potential risks. Therefore, a clinical evaluation is part of the compulsory risk management process according to ISO 14971, and critical findings must further be considered in the current risk management process of the medical device manufacturer responsible for the evaluated device.

On this background, the clinical evaluation was performed in order to comply with the current European medical device legislation, in particular with MEDDEV 2.7.1. This critical evaluation followed the procedures outlined in the corresponding clinical evaluation plan.

PalaXpress ultra is classified according to annex IX of council directive 93/42/EEC as a class IIa medical device.
PalaXpress ultra represents as well-known type of acrylic denture base material which has proven to exhibit the expected performance and clinical effectiveness. There is no hint for undesirable effect and potential risks when PalaXpress ultra is applied according to the instructions for use.
Considering the evaluated data and technical results for PalaXpress ultra it is concluded that the product will exhibit that claimed clinical and technical performance and that potential undesirable clinical effects and risks seem well controlled and acceptable when weighed against their benefits in dentistry. Therefore, the benefits versus risks ratio was stated to be positive for PalaXpress ultra, provided that the product is applied in accordance with its intended use according to the manufacturer's information for use.
Nevertheless, a risk for irritation or sensitization in susceptible patients or users due to the contact with PalaXpress ultra cannot be excluded.

The clinical report was carried out in accordance with MEDDEV 2.7.1 and followed the provisions of the corresponding clinical evaluation plan.

(c) Conclusion

The risk potential of the denture base resin PalaXpress ultra was proven. All properties of the product were verified successfully.

The biological compatibility of the denture base resin was investigated to evaluate the toxicological risk. A biological evaluation report has confirmed that the product PalaXpress ultra meets the requirements of ISO 10993 standard. The results were discussed in the biological evaluation report and the benefit / risk relation has been judge as positive.

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The physical properties of PalaXpress ultra were determined in accordance with ISO 20795-1 for denture base polymers. All properties comply with and exceed the requirements of the standard. This is stated in section (4).

Based on the results of the clinical evaluation report it is concluded that the product can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and acceptable when weighed against their benefits in dentistry.
The risk analysis according to ISO 14971 was carried out for PalaXpress ultra and showed that the application of the product according to the manufacturer's instruction for use can be considered as safe.

PalaXpress ultra meets all relevant requirements for denture base resins in accordance with the Medical Device Directive 93/42/EEC and National European medical device legislation. Based on the actual facts PalaXpress ultra is considered to be effective and safe when used in accordance with the manufacturer's instructions for use.

Wehrheim, April 29, 2011

Dr. K. Ruppert

A. Keishold

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Cheryl Zimmerman
Director, Quality Assurance & Regulatory Affairs
Heraeus Kulzer, LLC
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South Bend, Indiana 46614

APR 29 2011

Re: K110037
Trade/Device Name: PalaXpress Ultra
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: April 1, 2011
Received: April 6, 2011

Dear Ms. Zimmerman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110037

Device Name: **PalaXpress Ultra**

Indications for use:

Universal high fracture resistant denture base material. Used with injection or pouring techniques for fixed or removable dentures.

Injection procedure:
– Full maxillary and mandibular prostheses
– Implant over denture
Pouring procedure:
– Implant over denture
– Partial dentures. Multiple or single saddles
– Marginal contour and reshaping
– Repairs and additions
– Relines
– Dental splints

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110037